## SECTION 1.0
## INTRODUCTION

Appropriate use of pharmacotherapeutics during a pandemic may reduce morbidity and mortality, minimize social disruption, reduce economic impacts, and diminish the overwhelming demands that will be placed on the health care system. Pharmacotherapeutics might also be used during the Pandemic Alert Period to contain small disease clusters and potentially slow the spread of novel respiratory viruses. Pharmacotherapeutics may decrease severe complications from infection and reduce hospitalization.

Although efficacy has not been proven, for all respiratory viruses, pharmacotherapeutic prophylaxis may be used based on current CDC guidelines. These interventions are important when vaccines are unavailable and for those in whom vaccination may be medically contraindicated. A pandemic vaccine may be available in six months to one year into the pandemic.

The protection afforded by pharmacotherapeutic is virtually immediate and does not interfere with antibody response to inactivated vaccines.

During a pandemic, the demand for pharmacotherapeutics is likely to surpass the supplies available in the stockpiles. A large and uncoordinated demand for pharmacotherapeutics early in a pandemic could rapidly deplete national and local supplies. Planning for the optimal use of pharmacotherapeutics stocks is therefore essential. During a pandemic, DPHSS will need to play a central role in ensuring that limited supplies of pharmacotherapeutics will be distributed efficiently to where there is the greatest need and benefit. In addition, DPHSS will have to play a key role in giving guidance to healthcare providers about the use of pharmacotherapeutics (i.e., prophylaxis and treatment).

Due to space constraints, management logistics, and challenges with rotating stock, DPHSS will only be able to maintain a limited stockpile of pharmacotherapeutic. DPHSS SNS Coordinator or designee is responsible for coordinating and managing the Guam pharmacotherapeutic stockpile.

See Attachment 6-A.

## SECTION 2.0
## ESTABLISHING PRIORITY GROUPS

In situations where there are limited supplies of pharmacotherapeutics for any novel respiratory virus as advised by CDC, the pharmacotherapeutics should go to individuals who have the greatest need and are most likely to benefit from them.

Recommendations for priority groups for pharmacotherapeutics prophylaxis and treatment were provided by DHHS. This guidance for priority groups will most likely change depending on the epidemiological data (i.e., type of pandemic virus, drug supply, resistance pattern, etc.).

The highest priority should be the treatment of high-risk individuals who are hospitalized due to pandemic illness. The next would be (1) the treatment of healthcare workers with direct patient contact and EMS providers, and (2) the treatment of pandemic health responders, public safety workers, essential utility workers, and key government decision makers.

Only when there is an adequate supply of pharmacotherapeutics, will it be possible to provide treatment for low-risk outpatients and prophylaxis for high-risk outpatients and other high-risk healthcare workers who have no direct patient contact.

During the interpandemic and pandemic alert periods, DPHSS will coordinate and collaborate with the healthcare providers and form a standing committee - *Vaccine and Antiviral Prioritization Policy Committee (VAPPC)* to establish and refine "priority groups".

The VAPPC membership consists of:

- Office of the Governor designee
- DPHSS
    - Director
    - Medical Director
    - CHC Medical Director
    - Chief Public Health Officer
    - Chief Pharmacist
    - Territorial Epidemiologist
    - HPLO
    - Bureau of Communicable Disease Control
    - Public Health Emergency Preparedness Program
    - Guam Immunization Program
- Community Physicians comprising the following specialties:
    - Emergency Medicine
    - Critical Care
    - Infectious Disease

    - Internal Medicine
    - Family Medicine
    - Pediatrics
    - Geriatrics
- Health Professional Licensing Boards
- Guam Medical Society and/or Guam Medical Association Representative
- Government and Private Hospital Representatives:
    - Guam Memorial Hospital Authority (GMHA)
    - Guam Regional Medical City (GRMC)
- DOD Representatives

The VAPPC will define how a priority group will apply on a local level and will define who should be included in the groups of public safety workers, essential service providers, and key government decision makers.

The VAPPC will provide the rationale for establishing the priority groups so that the reasons for prioritization can be communicated to the community. In addition, the VAPPC will determine the projected use of pharmacotherapeutics during a pandemic on Guam using current CDC guidelines (i.e., treatment and prophylaxis).

During a novel respiratory virus pandemic, the VAPPC will modify these priority groups as needed based on the availability of pharmacotherapeutics and current CDC guidelines.

## SECTION 3.0
## CRITICAL ASSUMPTIONS

Assumptions regarding groups at highest risk during a pandemic and impacts on the healthcare system and other critical infrastructure are the same as those underlying the vaccine priority recommendations. Additional assumptions specific for pharmacotherapeutics include:

- Treating earlier after the onset of the disease is more effective in decreasing the risk of complications and shortening the illness duration. Generally, treatment should be given within the first 48 hours.
- The primary source of pharmacotherapeutics for a pandemic response will be the supply of pharmacotherapeutics that have been stockpiled.
- Assumptions for the number of pharmacotherapeutics needed for defined priority groups

are based on the population in those groups.

- For pharmacotherapeutics, the number of priority groups that can be covered would be based on the amount of drug that is stockpiled, unlike vaccines, where each tier would be protected in turn as more are produced. Some flexibility could be provided as more pharmacotherapeutics become available.

## SECTION 4.0
## STRATEGIES FOR PHARMACOTHERAPEUTICS USE IN A PANDEMIC – TREATMENT AND PROPHYLAXIS

**Treatment:**

Planning considerations include:

- Effectiveness of pharmacotherapeutics against new pandemic influenza or other novel respiratory virus cannot be predicted.

- Early treatment may reduce the risk of hospitalization.

- Early treatment is a more effective use of pharmacotherapeutics than widespread prophylaxis.

**Treatment Strategies:**

Optimal use of limited stocks of pharmacotherapeutics will vary depending upon the phase of the pandemic and current CDC guidelines.

- Modify priority groups for treatment based on current information on drug supplies, susceptibilities, fatality rates, age-specific mortality rates, and effectiveness of implemented strategies.

**Prophylactic Strategies:**

Planning considerations include:

- Limited supplies.

- Increased risk of side effects with prolonged use.

- Potential emergence of drug-resistant variants of the pandemic strain.

- Post-exposure prophylaxis might be useful in attempts to control small well-defined clusters (i.e., institutional outbreaks).

- The number of people who receive treatment with pharmacotherapeutics should be limited primarily to ensure that supplies are available to treat persons at the highest risk of serious morbidity and mortality.

- If sufficient supplies are available, prophylaxis should be used only during the periods of a pandemic to protect target groups such as health care workers, public safety, and other providers of essential utility services.

- Protect individuals with known recent exposure to the pandemic virus (i.e., household contact of a confirmed case).

- Modify priority groups for prophylaxis based on up-to-date information.

- Consider post-exposure prophylaxis to protect key personnel.

**Strategies for Combined Treatment and Prophylaxis:**

During a pandemic, combined pharmacotherapeutic - treatment for ill persons and targeted post exposure prophylaxis of contact would be considered in small disease clusters (i.e., households or institutions). Although, the administration of pharmacotherapeutics does not interfere with the development of antibodies to known pandemic viruses after the administration of the inactivated vaccine, the interference of other pharmacotherapeutics would have to be evaluated. Therefore, persons receiving prophylaxis can continue to receive any pharmacotherapeutic during the period between the vaccination and the development of immunity. Whether any pharmacotherapeutic can interfere with immune response elicited by the live attenuated vaccine is unknown.

**Pediatric Use:**

The decision by an individual physician to treat children under one year of age with an antiviral must be made on a case-by-case basis with full consideration of potential risks and benefits in compliance with FDA approved dosing for all ages

## SECTION 5.0
## DISTRIBUTING PHARMACOTHERAPEUTICS TO PRIORITY GROUPS

The distribution of pharmacotherapeutics will depend on the amounts of pharmacotherapeutics available on Guam, the priority groups that are to be targeted as recommended by the VAPPC, and the locations of greatest need. In order to equitably and effectively distribute pharmacotherapeutics to priority groups during a pandemic, DPHSS must rapidly direct their flow to the appropriate priority groups.

During the interpandemic period (Phases 1 – 2) and pandemic alert periods (Phases 3 – 5) DPHSS will:

- Work with stakeholders to develop a system to assess and track pharmacotherapeutic stocks.
- Establish the VAPPC.
- Work with private health clinics to plan for and exercise the distribution of pharmacotherapeutics based on priorities and needs.
- Establish the legal authority to have standing orders for pharmacotherapeutics.
- Explore how to implement standing orders if they are needed for the treatment of certain priority groups (i.e., hospitalized patients and health care workers).
- Review and update pre-existing plans for the transport, receipt, storage, security, tracking, and delivery of:
    - Pharmacotherapeutics for use in treatment to hospitals, clinics, nursing homes, alternate care facilities, and other health care institutions.
    - Pharmacotherapeutics for use in post-exposure prophylaxis (i.e., for direct contacts of infected patients).
    - Pharmacotherapeutic for use in prophylaxis even when there is no known direct pandemic exposure (i.e. pandemic health responders, public safety workers, essential utility workers, and key government decision makers).
    - During a pandemic, requests for pharmacotherapeutics will be handled through an ICS.
    - Providers will request pharmacotherapeutics through the EOC and the distribution will be guided by the VAPPC's recommendation for priority groups.

## SECTION 6.0
## POINTS OF DISTRIBUTION

DPHSS SNS Coordinator or designee will coordinate the main pharmacotherapeutic distribution site. The distribution site will be determined based on current SNS plan.

Additional points of distribution for pharmacotherapeutics would include the hospitals, private clinics, and pharmacies.

## SECTION 7.0
## LEGAL PREPAREDNESS

During a pandemic, there may be a need for the DPHSS Medical Director to issue blanket prescriptions for dispensing and distributing pharmacotherapeutics. The DPHSS Medical Director

would need the authority to do so in a way that is consistent with Guam's prescription laws.

DPHSS needs to establish legal authority to dispense pharmacotherapeutics per standing order at the health department level.

In addition, there needs to be clarification as to whether adverse side effects of pharmacotherapeutics, when taken for prophylaxis by essential workers, would be covered by the Worker's Compensation Law.

## SECTION 8.0
## TRAINING

To assist healthcare providers in identifying and managing a pandemic, current CDC guidelines for healthcare providers will be posted on the DPHSS website

In addition, DPHSS will involve the VAPPC and its stakeholders in conducting exercises on how to distribute the pharmacotherapeutics on priority needs.
DPHSS will also implement an educational plan for the general public which is as follows:

- Role of pharmacotherapeutics in responding to a pandemic.
- Need to prioritize limited pharmacotherapeutic supplies for treatment and prophylaxis.
- Importance of appropriate use (i.e., using the drug for a full number of days recommended to minimize the development of drug resistance).

## SECTION 9.0
## CONTINGENCY PLAN FOR INVESTIGATIONAL DRUG USE

Unlicensed pharmacotherapeutics may be available under the U.S. Food and Drug Administration's (FDA) Investigational Drug (IND) provision during a pandemic.

The U.S. FDA regulations permit the use of a national or "Central Institutional Review Board (IRB)" for IND medications and would likely be used in such a situation.

Alternative to IND, the US CDC may utilize the drug product under emergency use authorization procedures as described in the FDA draft guidance "Emergency Use Authorization of Medical Products".

## SECTION 10.0
## ACTIVATION

The actual activation of the Plan will begin when Phase IV is declared.

## PANDEMIC PHASES

### WHO PHASE 1/PANDEMIC CONDITION OF READINESS 4 (PCOR4): INTERPANDEMIC PERIOD

- **DPHSS**
    - Focus on preparedness planning for the rapid distribution and use of pharmacotherapeutics and education of the healthcare providers about pharmacotherapeutic use in the phase of a pandemic.
    - Keep abreast of the development, evaluation, production, and availability of pharmacotherapeutics n the U.S.
    - Ensure that mechanisms are in place for the acquisition and procurement of pharmacotherapeutics.
    - Coordinate and collaborate with healthcare providers and form a standing committee, the VAPPC, to establish and refine priority groups.
    - Convene the VAPPC consisting of medical professionals and allied health practitioners.
    - Ensure the strategic plan for the storage, management, use and rapid distribution of pharmacotherapeutics is in accordance with current CDC guidelines.
    - Identify existing storage capabilities.
- **VAPPC**
    - Throughout the pandemic period, education of healthcare providers will continue and be facilitated by the VAPPC. DPHSS's recommendations for the optimal use of pharmacotherapeutics will be updated throughout the course of the pandemic to reflect new epidemiological data, laboratory results, and the availability of an effective pandemic vaccine.
    - Establish a list of priority populations involved in the pandemic response activities, maintenance of critical services, and health infrastructure for pharmacotherapeutic prophylaxis.

### WHO PHASE 2/PCOR4: INTERPANDEMIC PERIOD

- **DPHSS**
    - In collaboration with the VAPPC, will develop a communication plan to explain the rationale for the target group for pharmacotherapeutic treatment or prophylaxis.

- Identify POC and POD that would be needed to administer the pharmacotherapeutics (i.e., hospitals, private clinics, community health centers, nursing homes, pharmacies).

- Initiate order of pharmacotherapeutics for stockpile, if available.

- **VAPPC**

  - Establish a list of priority populations involved in the pandemic response activities, maintenance of critical services, and health infrastructure for pharmacotherapeutic prophylaxis.

  - Review the current information on the use, effectiveness, safety, and the development of drug resistance of pharmacotherapeutics.

  - Review modifications, if any, to interim recommendations on pharmacotherapeutic prophylaxis in selected groups or circumstances.

### WHO PHASE 3/PCOR3: PANDEMIC ALERT PERIOD

- **DPHSS**

  - Follow-up allocation of pharmacotherapeutics.

  - Maintain a tracking system to monitor the use, efficacy, and adverse events of pharmacotherapeutics.

  - Develop a standing order for antiviral distribution to the priority groups for treatment or prophylaxis.

  - Establish legal authority to have standing orders for pharmacotherapeutics at the health department level.

  - Continue to assess status of available pharmacotherapeutics and strategies for use.

  - Coordinate with VAPPC to accelerate training on the appropriate use of pharmacotherapeutics among public health staff and health care partners.

### WHO PHASE 4/PCOR2: PANDEMIC ALERT PERIOD

- **DPHSS**

  - Receive, store, and stage at the designated site.

- Work with other government agencies, and non-governmental organizations (NGO) to ensure effective public health communication.

- **VAPPC**

  - Review and revise, as needed, priority groups and strategies for pharmacotherapeutic drug use.

  - Monitor current information on the pharmacotherapeutic resistance of the pandemic strain.

  - Maintain updates of treatment guidelines, as recommended by the CDC.

### WHO PHASE 5/PCOR2: PANDEMIC ALERT PERIOD

- **DPHSS**

  - Prepare for the rapid distribution of pharmacotherapeutics through pre-identified POC and POD sites.

  - Handle request for pharmacotherapeutics through PHIC.

  - Establish and maintain inventory of pharmacotherapeutics.

  - Establish and maintain a registry of individuals in priority population receiving pharmacotherapeutics.

  - Monitor adverse events in persons receiving pharmacotherapeutics.

### WHO PHASE 6/PCOR1: PANDEMIC PERIOD

- **DPHSS**

  - Distribute pharmacotherapeutics through pre-identified POC and POD sites.

  - Monitor drug distribution and use, assess whether pharmacotherapeutics are effectively being targeted to priority groups.

  - Enrollment of providers and conduct training of physicians for direct dispersal.

- **VAPPC**

  - Modify priority groups based on the availability of pharmacotherapeutics,

characteristics of the causative virus, and effectiveness of the implemented strategy.

## POSTPANDEMIC PERIOD

- **DPHSS**
    - Assess supply status and any imminent needs.
    - Prepare report assessing pharmacotherapeutics delivery response.
- **VAPPC**
    - Revert to interpandemic activities.